SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Automated External Defibrillator

Device Trade Name: AED Battery Exchange (Models 9146-ABE, G5-ABE, 5070-ABE, FR3-ABE)

Device Procode: MKJ, NSA

Applicant's Name and Address: AED Battery Exchange, LLC
1000 Brown Street, Suite 206
Wauconda, Illinois 60084

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P190013

Date of FDA Notice of Approval: February 2, 2021

AED Battery Exchange, LLC remanufactured (or "re-celled") batteries have been on the market in the US since 2012, when FDA issued clearance through the 510(k) Premarket Notification process (K120350, "Extended Life Battery"). Compatible AEDs at the time of K120350 clearance included the Cardiac Science Powerheart AED G3 and the Philips FRx, Onsite/Home, and FR3. P190013 has been submitted in response to the *Final Order* issued January 29, 2015, in the Federal Register Volume 80 Number 19, Docket No. FDA-2013-N-0234 and republished February 3, 2015, in the Federal Register Volume 80 Number 22, Docket No. FDA-2013-N-0234. This Order required premarket approval of marketed pre-amendment Class III Automated External Defibrillator (AEDs) and Accessories (e.g., batteries, electrode pads). Products affected by this Order are the AED Battery Exchange 9146-ABE and 5070-ABE. Please note that the AED Battery Exchange G5-ABE and FR3-ABE were not pre-amendment Class III AED accessories and are requesting marketing approval for the first time in P190013. A combination of relevant literature and in-vitro bench testing has been reviewed to demonstrate a reasonable assurance of safety and effectiveness for the AED Battery Exchange, models 9146-ABE, G5-ABE, 5070-ABE, and FR3-ABE.

II. INDICATIONS FOR USE

The automated external defibrillator (AED) battery supplies power to an AED as required during self maintenance, automated diagnoses, and defibrillation. The 9146-ABE is indicated for use with the Cardiac Science Powerheart G3, models 9390A, 9390E, 9300A, and 9300E. The G5-ABE is indicated for use with the Cardiac Science Powerheart G5, models G5A-80A, G5A-80C, G5S-80A, and G5S-80C. The 5070-ABE is indicated for use with the Philips HeartStart OnSite/Home, models M5066A, M5068A, and the FRx, model

861304. The FR3-ABE is indicated for use with the Philips HeartStart FR3, models 861388 and 861389.

III. CONTRAINDICATIONS

Automated external defibrillators should not be used when a patient is conscious or breathing normally.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the AED Battery Exchange labeling.

V. DEVICE DESCRIPTION

The 9146-ABE, G5-ABE, 5070-ABE, and FR3-ABE are primary batteries (non-rechargeable) that provide power to AEDs during self maintenance, automated diagnoses and defibrillation. Table 1 lists the four (4) battery models and their compatible AEDs.

Table 1: AED Battery Exchange (Models 9146-ABE, G5-ABE, 5070-ABE, and FR3-ABE)

	Compatible AEDs	**Description**
9146-ABE 	Cardiac Science™ Powerheart® G3 models 9390A, 9390E, 9300A, 9300E (P160033)	Lithium-Sulfur Dioxide (Li-SO2), 12 V, 7.5 A h
G5-ABE 	G5-ABE: Cardiac Science™ Powerheart® G5 models G5A-80A, G5A-80C, G5S-80A, G5S-80C (P160033)	Lithium-Sulfur Dioxide (Li-SO2), 12 V, 7.5 A h
5070-ABE 	Philips™ HeartStart™ Onsite/Home models M5066A, M5068A (P160029); FRx model 861304 (P160028)	Lithium Manganese Dioxide (LMnO2), 9 V, 4.2 A h

	Compatible AEDs	Description
FR3-ABE 	Philips™ HeartStart™ FR3 models 861388 and 861389 (P180028)	Lithium Manganese Dioxide (LMnO2), 9 V, 4.2 A h

AED batteries must be installed in a compatible AED before they can be used. When installed, compatible AEDs are intended for use by personnel trained in their operation (Cardiac Science Powerheart® G3 models 9390A, 9390E, 9300A, 9300E; Cardiac Science™ Powerheart® G5 models G5A-80A, G5A-80C, G5S-80A, G5S-80C); users who have received training basic life support/AED or as part of a physician-authorized emergency medical response training program (Philips™ HeartStart™ FRx model 861304); users who have received training in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized training program (Philips™ HeartStart™ FR3 models 861388 and 861389); and lay-persons (Philips™ HeartStart™ Onsite/Home models M5066A, M5068A) to treat victims of sudden cardiac arrest.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Defibrillation is the only currently available treatment for termination of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). Public access defibrillation is designed to provide potentially lifesaving treatment prior to the arrival of emergency personnel.

VII. MARKETING HISTORY

The 9146-ABE and 5070-ABE have been commercially available in the US since 2012, cleared under K120350. The G5-ABE and FR3-ABE have not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device and AEDs in general, listed in decreasing order of seriousness:

- Failure to identify shockable arrhythmia;
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction;
- Myocardial damage;

- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents;
- Electromagnetic interference (EMI) from the defibrillator impacting other devices especially during charge and energy transfers;
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest;
- Bystander shock from patient contact during defibrillation shock;
- Interaction with pacemakers;
- Skin burns around the electrode placement area;
- Allergic dermatitis due to sensitivity to materials used in electrode construction; and
- Minor skin rash.

IX. SUMMARY OF NONCLINICAL STUDIES

Bench Testing

Through risk assessment conducted as part of a risk management process in alignment with the FDA-recognized voluntary consensus standard ISO 14971:2019, relevant hazards and estimated risks associated with the specific manufacturing procedure for remanufacturing the batteries were identified, in consideration of the performance of the original equipment manufacturer (OEM) batteries. Risk control measures were then identified and verified through non-clinical bench performance testing, which included selective application of relevant clauses from FDA-recognized voluntary consensus standards and other consensus standards. Table 2 summarizes design verification and design validation activities conducted to demonstrate a reasonable assurance of safety and effectiveness for the AED Battery Exchange (Models 9146-ABE, G5-ABE, 5070-ABE, FR3-ABE).

Table 1: **Bench Testing**

Test Title	**Acceptance Criteria**	**Results**
Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010/(R)2015)	Acceptance criteria as specified by Subclause 201.101.2 – Requirements for INFREQUENT USE, MANUAL DEFIBRILLATORS and Subclause 201.1.2.2 – Requirements for MANUAL DEFIBRILLATORS	Acceptable
Drop Test	Conducted in accordance with IEC 60601-1:2012 and in consideration of ANSI/AAMI ES60601-1:2005 + A1:2012, Subclause 15.3.4. Tests	Acceptable

Test Title	Acceptance Criteria	Results
	conducted within OEM AED and as a stand-alone battery.	
Shock Cycle Count Verification	Minimum shock cycle count verified using specifications of OEM batteries.	Pass
Operation Time Verification	Minimum operation time verified using specifications of OEM batteries.	Pass
Storage Temperature Verification	Storage temperature verified using specifications of OEM batteries.	Pass
Charge State Recognition	Charge state recognition verified for conformity with IEC 60601-2-4:2010/(R)2015, Subclause 201.15.4.3.101 using OEM AED.	Pass
Label Integrity Verification	Conducted in accordance with IEC 60601-1:2012 and in consideration of ANSI/AAMI ES60601-1:2005 + A1:2012	Pass
Software Verification	Conducted in accordance with FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."	Acceptable
Enclosure Protection (IEC 60529)	Ingress Protection (IP) ratings evaluated using specifications of OEM batteries.	Pass
EMC Verification by Component Analysis	N/A	Acceptable
Shelf Life Verification by Component Analysis	N/A	Acceptable

Test Title	Acceptance Criteria	Results
Thermal Extreme (UN38.3)	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass
Vibration (UN38.3)	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass
Shock Safety (UN38.3)	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass
External Short Circuit Safety (UN38.3)	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass
Altitude Safety (UN38.3)	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass
Label Integrity Verification	Conducted in accordance with IEC 60601-1:2012.	Pass
Software Verification	Conducted in accordance with FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 2005.	Pass

Test Title	Acceptance Criteria	Results
Packaging (UN38.3 tested), 49 CFR compliant for US ground transportation	Conducted in accordance with "Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria," Section 38.3.	Pass

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The final order, Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems, published on January 29, 2015 and republished on February 3, 2015, states that clinical study information can be leveraged for AEDs from both published studies and clinical data previously submitted to FDA under the 510(k) Premarket Notification process. AED Battery Exchange, LLC did not submit clinical data in support of a reasonable assurance of safety and effectiveness. Data supportive of a reasonable assurance of safety and effectiveness is available in the compatible AED Summaries of Safety and Effectiveness Data:

P160028: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160028B.pdf

P160029: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160029B.pdf

P160033: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160033B.pdf

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel on January 25, 2011 as part of the 515(i) process. The majority of the panel recommended that AEDs be regulated as Class III PMAs to have better oversight of device manufacturing and post-market performance.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Benefits of use of the batteries with their specific AEDs outweigh the risks with which it is associated. This is verified through the longevity of the commercialization of the products, through the literature on clinical safety and effectiveness, and through the post-market data, including tracking and trending of complaints and vigilance.

B. **Safety Conclusions**

The nonclinical testing and data collected on the battery models 9146-ABE, 5070-ABE, G5-ABE, and FR3-ABE in use with their respective AEDs did not identify or result in any unacceptable safety concerns associated with use of the AED Battery Exchange Models 9146-ABE, 5070-ABE, G5-ABE, and FR3-ABE.

C. **Benefit-Risk Determination**

The benefit of early defibrillation therapy is the survival of patients in sudden cardiac arrest (SCA). The time from collapse to defibrillation is critical in patient survival. For every minute that passes between collapse and defibrillation, survival rates from ventricular fibrillation (VF) SCA decrease by 7% - 10%.

The magnitude of this benefit is either life or death. Patients are likely to put a high value on this treatment because it has the potential to save their lives. Patients are therefore willing to accept the risks of this treatment to achieve the benefit. If the treatment provides timely successful defibrillation, the patient will (or may) survive a life-threatening cardiac arrest situation and will be able to seek further treatment.

1. Patient Perspectives: This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data support that for the AED Battery Exchange 9146-ABE (when used with the Cardiac Science Powerheart G3, models 9390A, 9390E, 9300A, and 9300E); the AED Battery Exchange G5-ABE (when used with the Cardiac Science Powerheart G5, models G5A-80A, G5A-80C, G5S-80A, and G5S-80C); the AED Battery Exchange 5070-ABE (when used with the Philips HeartStart OnSite/Home, models M5066A, M5068A, and the FRx, model 861304); and the AED Battery Exchange FR3-ABE (when used with the Philips HeartStart FR3, models 861388 and 861389), the probable benefits outweigh the probable risks.

D. **Overall Conclusions**

The data in this application support the reasonable assurance of safety and effectiveness of the AED Battery Exchange 9146-ABE (when used with the Cardiac Science Powerheart G3, models 9390A, 9390E, 9300A, and 9300E); the AED Battery Exchange G5-ABE (when used with the Cardiac Science Powerheart G5, models G5A-80A, G5A-80C, G5S-80A, and G5S-80C); the AED Battery Exchange 5070-ABE (when used with the Philips HeartStart OnSite/Home, models M5066A, M5068A, and the FRx, model 861304); and the AED Battery Exchange FR3-ABE (when used with the Philips HeartStart FR3, models 861388 and 861389), respectively, when used in accordance with the indications for use.

XIII. CDRH DECISION

CDRH issued an approval order on February 2, 2021.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.